Supreme Court, U.S.
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Nos. 96-562, 96-575

IN THE SUPREME COURT OF THE UNITED STATES

October Term, 1996

ORGANON, INC.,

Petitioner,

v.

DAVID A. KESSLER, M.D., ET AL.,

Respondents.

BRACCO DIAGNOSTICS INC., ET AL.,

Petitioners,

v.

DAVID A. KESSLER, M.D., ET AL.,

Respondents.

On Petitions for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF RESPONDENTS MERCK & CO., INC., MSD TECHNOLOGY, L.P. and SCHERING CORPORATION IN OPPOSITION

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24 pp

QUESTIONS PRESENTED

The only questions decided adversely to petitioners by the Court of Appeals for the Federal Circuit arise under the Hatch-Waxman Act, 35 U.S.C. § 156, which authorizes patent term restoration for patents covering pharmaceutical products whose marketing has been delayed by the regulatory approval requirements of the Federal Food, Drug, and Cosmetic Act. Those questions are:

1. Would the statutory bar of multiple Hatch-Waxman patent term restoration periods be violated in cases where the patent was in force on June 8, 1995, solely by virtue of a Hatch-Waxman term restoration period if a Hatch-Waxman restoration period is added to the term of 20 years from filing of the patent application that was established by the Uruguay Round Agreements Act ("URAA")?

2. Would the 24-month limitation on certain Hatch-Waxman patent term restoration periods be exceeded

in cases where the patent was in force on June 8, 1995, solely by virtue of the Hatch-Waxman restoration period if a 24-month Hatch-Waxman restoration period is added to the term of 20 years from filing of the patent application that was established by the URAA?

LIST OF PARTIES

This Opposition to Petitions for Writ of Certiorari is filed on behalf of Merck & Co., Inc., MSD Technology, L.P. and Schering Corporation. The parent company, non-wholly owned subsidiaries, and affiliates of Merck & Co. that have issued shares to the public are:

Banyu Pharmaceutical Co., Limited
Banyu ASC Co., Ltd.
Nippon Merck Banyu Co.Ltd.
Prodome Quimica e Farmacaeutica Ltda.
Kronans Droghandel AB
Kiineiesto Oy Irmelinpesa
Comnet Corporation

MSD Technology, L.P. is a limited partnership, comprised of four partners, three of which are wholly-owned subsidiaries of Merck & Co., Inc. The fourth partnership interest in MSD Technology, L.P. is held by Abbey National Treasury Services, P.L.C.

The parent company, non-wholly owned subsidiaries, and affiliates of Schering Corporation that have issued shares to the public are: Schering-Plough Corporation.

Other parties to the proceedings in the United States Court of Appeals for the Federal Circuit were: Bracco Diagnostics Inc. and Bracco International B.V.; Hoffmann-La Roche Inc. and Syntex (U.S.A.) Inc.; Organon, Inc.; David A. Kessler, M.D., Commissioner of Food and Drugs; Bruce A. Lehman, Assistant Secretary of Commerce and Commissioner of Patents and Trademarks; and the Generic Pharmaceutical Industry Association.

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BRIEF OF RESPONDENTS MERCK & CO., INC., MSD TECHNOLOGY, L.P. and SCHERING CORPORATION IN OPPOSITION

STATUTES INVOLVED

The only statutory issues decided adversely to petitioners by the court below arise under two subsections of the Hatch-Waxman Act, 35 U.S.C. §§ 156(a)(2) and 156(g)(6)(C).

STATEMENT OF THE CASE

The two petitions before the Court originated in five cases brought before the United States District Court for the Eastern District of Virginia to contest the refusal of the Food and Drug Administration ("FDA") to publish patent expiration dates claimed for 12 patents. In each case, the plaintiffs claimed entitlement to add a Hatch-Waxman restoration period to a patent term of 20 years from filing of the patent application that was authorized for patents in force on June 8, 1995, by Section 154(c)(1) of the Patent Act, 35 U.S.C. § 154(c)(1), as added to the law by the URAA.

In the URAA, Congress eliminated the former patent term of 17 years from grant in favor of a term of 20 years from filing, effective with patents applied for on or after June 8,

1995.[1] A transitional provision requires that the term of each patent in force on June 8, 1995, or that results from an application filed before that date, "shall be the greater" of 17 years from grant or 20 years from filing. 35 U.S.C. § 154(c)(1). Apart from one amendment to Section 156(a)(2), Congress left unchanged the provisions of the Hatch-Waxman Act that add restoration periods[2] to the terms of patents covering products, such as drugs, subject to pre-market regulatory delay by the FDA.[3] *See generally Bristol-Myers*

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[1] 35 U.S.C. § 154(a)(2), Pub. L. 103-465, Title V, §§ 532(a)(1), 534.

[2] The period of Hatch-Waxman patent term restoration does not recover the full time lost to the FDA's pre-market approval process, but merely "ameliorate[s] the loss incurred when patent terms tick away while the patented product is awaiting regulatory approval for marketing" by the FDA. *Unimed, Inc.* v. *Quigg*, 888 F.2d 826, 829, 12 U.S.P.Q.2d (BNA) 1644, 1647 (Fed. Cir. 1989). Because a considerable part of the effective life of a patent can be consumed by the FDA regulatory processes, the Hatch-Waxman Act provides holders of pharmaceutical patents with term restoration to "reward a patentee for research and development efforts by extending the life of a patent covering an innovative new drug whose marketing was delayed by FDA regulatory review." *Glaxo Operations U.K. Ltd.* v. *Quigg*, 706 F. Supp. 1224, 1229 (E.D. Va. 1989), *aff'd*, 894 F.2d 392, 13 U.S.P.Q.2d (BNA) 1628 (Fed. Cir. 1990).

[3] If the patent was issued and human testing began before the 1984 enactment of the Hatch-Waxman Act, the maximum permitted restoration period is two years. Otherwise, the restoration period is in most cases

(continued...)

Squibb Co. v. *Royce Laboratories*, 69 F.3d 1130, 1136-37, 36 U.S.P.Q.2d (BNA) 1641, 1647-48 (Fed. Cir. 1995), *cert. denied*, ___ U.S. ____, 116 S.Ct. 754 (1996); *DuPont Merck Phar. Co.* v. *Bristol-Myers Squibb Co.*, 62 F.3d 1396, 1402, 35 U.S.P.Q.2d (BNA) 1718 (Fed. Cir. 1995). The sole URAA amendment to Section 156(a)(2) provides that only a prior Hatch-Waxman patent term restoration period disqualifies a patent from further term restoration under Hatch-Waxman. *See* 35 U.S.C. § 156(a)(2).

The district court ruled for all the plaintiffs as to all 12 patents. The Court of Appeals for the Federal Circuit thereafter reversed the determination of the district court as to

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[2/](...continued)
limited to five years. 35 U.S.C. § 156(g)(6)(C); *Cf. Hoechst Aktiengesellschaft* v. *Quigg*, 917 F.2d 522, 16 U.S.P.Q.2d (BNA) 1549 (Fed. Cir. 1990). All patents in suit other than petitioner Organon's U.S. Patent No. 3,927,046 (the "'046 patent') are subject to the two-year limitation on patent term restoration.

For all patents receiving Hatch-Waxman term restoration, the effective patent life, including the patent term restoration period, may not exceed 14 years following FDA approval of the product for commercial marketing. 35 U.S.C. § 156(e)(3).

five of the patents. Petitioners Bracco and Organon each hold one of the five patents adversely affected by the decision below. The other three are held by respondents Hoffmann-La Roche and Syntex (together "Roche"), which have not sought review in this Court. Each of these five patents was in force on June 8, 1995, solely by virtue of a Hatch-Waxman restoration period, as the pre-URAA term of 17 years from grant had ended prior to June 8, 1995. No more than three dozen additional patents are in similar circumstances.[4/]

Respondents Merck and Roche each hold three and respondent Schering holds one of the other seven patents in suit. The district court ruling was affirmed below as to each of these seven patents.

The Federal Circuit held in its decision of April 4, 1996, that holders of pharmaceutical patents may add a patent term

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[4/] The decision complained of in the petition can affect only patents satisfying two criteria: the patent was in force on June 8, 1995 solely by virtue of a previously authorized Hatch-Waxman patent term restoration period, and the patent was granted less than three years after the patent application was filed. Publicly available data show approximately forty patents that satisfy these criteria.

restoration period previously certified under the Hatch-Waxman Act to the term of 20 years from filing established by Section 154(c)(1) of the Patent Act, 35 U.S.C. § 154(c)(1), as added by the URAA, subject only to specific limitations established in the Hatch-Waxman Act itself. On the basis of two of those limitations, the court below held that patents whose pre-URAA 17-year term had expired prior to June 8, 1995 and were "in force on June 8, 1995, only because of a restoration extension" are not eligible for a 20-years-from-filing term plus a Hatch-Waxman restoration period. *Merck & Co.* v. *Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996). (96-562 Pet. App. 15a).[5/]

[5/] In accordance with petitioners' contentions below, the Federal Circuit concluded that under Section 154(c)(1) "pre-June 8, 1995, patents are entitled to add on the restoration extension to a 20-year from filing term regardless of when such extension is granted . . . ." *Merck & Co.* v. *Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996). (96-562 Pet. App. 15a). Accordingly, petitioners may seek review only of that part of the ruling that identified an exception for patents such as Bracco's U.S. Patent No. 4,001,323 (the "'323 patent") and Organon's '046 patent that would have expired prior to June 8, 1995 in the absence of Hatch-Waxman term restoration. *Id.*

The Federal Circuit based the latter result on two statutory sections that limit the availability of Hatch-Waxman Act patent term restoration periods. First, the Federal Circuit relied on Section 156(a)(2) of the Hatch-Waxman Act, which limits Hatch-Waxman patent term restoration to cases where "the term of the patent has never been extended" under the Hatch-Waxman Act. The court reasoned:

> The terms of these five patents have once been extended under [Hatch-Waxman] . . . . A reapplication of the restoration extension would constitute a second extension contrary to the statute.

Id. at 1552. (96-562 Pet. App. 21a).

Second, the Federal Circuit concluded that because part of the Hatch-Waxman restoration period had run prior to June 8, 1995, addition of the full 24-month restoration period of petitioner Bracco's '323 patent to the 20-years-from-filing term of Section 154(c)(1) would violate the 24-month limitation that Section 156(g)(6)(C) places on term restoration for that patent. The court below held:

> For example, U.S. Patent No. 4,001,323 would have expired on January 4, 1994, before enactment of the URAA. It received the maximum [Hatch-Waxman] extension of two years and had used 17 months of that extension as of June 8, 1995. Under the district court's interpretation, the patentee is entitled to the two-year extension added to a 20-year term. The restoration extension totals 41 months which exceeds the statutory limit of 24-months.

Id.

REASONS FOR DENYING THE WRIT

No issue of general importance is raised in these cases, there is no conflict with any Supreme Court decision, and there is not and never will be a conflict of decisions among the courts of appeals. The Federal Circuit's decision adverse to petitioners turns on a narrow issue of statutory construction that affects no more than a handful of patents and even that small number is dwindling with time. The petitions therefore present no issue worthy of this Court's review.

1. The Federal Circuit's decision adverse to petitioners affects only those pharmaceutical patents that were in force on

June 8, 1995 solely by virtue of a Hatch-Waxman patent term restoration period. Only a small number of patents could ever have fallen into this category and therefore could have been affected by the decision below.[6/] Moreover, the number of patents whose terms would be affected by a decision of these issues by this Court becomes smaller with the passage of time. Already, a number of those patents would have expired even under the legal theory petitioners advance.[7/]

To secure review by this Court in the absence of a conflict among circuits, petitioners must demonstrate both that there is a substantial basis for believing the court below erred in its construction of the governing statute and that the issue has substantial importance. *See* Sup. Ct. R. 10(c) (among the considerations governing review on certiorari is when "a federal court of appeals has decided an important question of

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[6/] *See* n. 4 *supra*.

[7/] An example is provided by petitioner Organon's '046 patent, which would have expired on November 6, 1996, under petitioners' legal theory. *See* pp. 14-15 *infra*.

federal law which has not been, but should be, settled by this Court . . ."). This showing is one petitioners cannot make, and they therefore do not meet the demanding standards that govern the issuance of a writ of certiorari.[8/]

2. The decision of the Federal Circuit does not conflict with any decision of this Court or any other court of appeals. Nor could there ever be such a conflict among the circuits, as the issues presented are within the exclusive jurisdiction of the Federal Circuit under 28 U.S.C. § 1295(a)(1).

3. Petitioners are incorrect in contending that the Federal Circuit's decision re-writes the language of Section 154(c)(1) of the Patent Act, 35 U.S.C. § 154(c)(1). (See 96-575 Pet. at 12 and 14; and 96-562 Pet. at 8-9). As the

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[8/] The lack of importance of the issues decided below is further shown by the decision of the Solicitor General not to seek review of the parts of the Federal Circuit's decision that were adverse to the Government's contentions. Similar decisions were made by respondent Generic Pharmaceutical Industry Association, a trade association of generic pharmaceutical manufacturers, which vigorously supported the Government's position below, and by Roche, which is the owner of three of the five patents whose terms were adversely affected by the aspects of the Federal Circuit's decision of which petitioners complain.

Federal Circuit's opinion recognized, Section 154(c)(1) is "a transitional provision" that permits every patent whose term was "in force" on June 8, 1995 "to enjoy the 17-year term from issuance of the patent or a 20-year from filing term, whichever is longer." *Merck & Co.* v. *Kessler*, 80 F.3d 1543, 1547-48 (1996). (96-562 Pet. App. 15a).

The Federal Circuit's reversal of the favorable judgment that petitioners secured in the district court focused not on Section 154(c)(1), but upon two subsections that the Hatch-Waxman Act incorporated in Section 156 of the Patent Act, 35 U.S.C. § 156. Under that court's analysis, the dispositive fact in petitioners' cases was that their patents were in force on June 8, 1995, only because the Hatch-Waxman restoration periods of those patents had come into operation prior to June 8, 1995.

In relying upon Section 156(a)(2), which "provides that a [Hatch-Waxman] restoration extension may be given provided 'the term of the patent has never been extended under

subsection (e)(1) of this section,'" the court cited the fact that petitioners' patents already had "once been extended under subsection (e)(1)" prior to the June 8, 1995, effective date of the URAA. *Merck & Co.* v. *Kessler*, 80 F.3d 1543, 1552 (Fed. Cir. 1996). (96-562 Pet. App. 21a). The decision concludes that "re-application of the restoration extension" at the end of the 20-year term "would constitute a second extension contrary to the statute." *Id.*

In alternatively relying upon Section 156(g)(6)(C), which limits the length of any Hatch-Waxman restoration of the terms of patents such as Bracco's '323 patent to two years, the court below concluded that addition of the Hatch-Waxman extension to the URAA term of 20 years from filing would result in a Hatch-Waxman term restoration extension exceeding "the statutory limit of 24 months" imposed by Section 156(g)(6)(C). *Id.*

The Federal Circuit fully sustained petitioners' contentions on every other issue, including the interpretation of other

relevant parts of the Hatch-Waxman Act and Section 154(c), as added by the URAA. Thus, the Federal Circuit held that all patents in suit, including those of petitioners Bracco and Organon, were "in force on June 8, 1995." *Id.* at 1548. (96-562 Pet. App. 9a). The Federal Circuit further sustained petitioners' contention that the phrase "original expiration date" in Section 156(a) "means no more than that the expiration date has not been extended under section 156(e)(1)" of the Hatch-Waxman Act. *Id.* at 1551. (96-562 Pet. App. at 15a). Accordingly, no issue under the URAA was resolved adversely to petitioners' contentions and, therefore, they have no such issue to raise before this Court.

4. Petitioner Organon does not present an issue available for review on certiorari in its argument that the FDA in effect modified its own regulations in violation of the Administrative Procedure Act ("APA") when it refused to publish patent expiration dates tendered by petitioners. (96-562 Pet. App. at 12-20). While respondents Merck and Schering agree that the

FDA's action was at odds with its own regulation governing publication of patent expiration dates claimed by holders of pharmaceutical patents, *see* 21 C.F.R. § 314.53(e) (1995) (96-562 Pet. App. 195a), the violation was not approved by the Federal Circuit. Indeed the Federal Circuit's ruling in favor of respondents Merck and Schering necessarily overrules the FDA's action and the Federal Circuit did not in any fashion rely upon the FDA regulation in ruling against petitioners. Therefore, the APA issue is not fairly presented for further review.

5. Organon's petition should be denied for the further reason that it is moot. Under the Federal Circuit's decision, Organon's '046 patent expired nearly a year ago, on November 19, 1995. Under the statutory theory that Organon advanced below and argues in its petition for certiorari, the life of the patent would be extended only to November 6, 1996. Since the latter date has come and gone, any grant of a writ of certiorari and subsequent proceedings on the merits

of the case would occur only after the patent expiration date for which Organon contends. Furthermore, Organon does not claim to have rights to any other patent that would be affected by further review of the Federal Circuit's decision. As a result, Organon's case has become moot. *See Lewis* v. *Continental Bank Corp.*, 494 U.S. 472, 477-78 (1990) (Supreme Court jurisdiction dependent on continued interest of parties in outcome of case); *Deakins* v. *Monoghan*, 484 U.S. 193, 199 (1988) (Article III jurisdiction limited to "actual ongoing controversies").

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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November 8, 1996